

Fact Sheet



For Final Renewal Permitting Action Under 45CSR30 and Title V of the Clean Air Act

Permit Number: **R30-06100033-2012**

Application Received: **June 13, 2011**

Plant Identification Number: **061-00033**

Permittee: **Mylan Pharmaceuticals Inc.**

Facility Name: **Morgantown**

Mailing Address: **781 Chestnut Ridge Road, Morgantown, WV 26505**

Revised: N/A

Physical Location:	Morgantown, Monongalia County, West Virginia
UTM Coordinates:	589.6 km Easting • 4390.1 km Northing • Zone 17
Directions:	I-79 to Exit 155. Follow signs for WVU. Follow US Route 19 to Coliseum. Turn left onto SR 705 for approximately 1.2 miles. Turn right to stay on SR 705 (Chestnut Ridge Road). Follow for approximately 0.6 miles to plant on left.

Facility Description

Mylan Pharmaceuticals Inc. is a batch pharmaceutical manufacturing company. Mylan purchases raw materials from suppliers and performs various quality control tests on the raw materials. The manufacturing plant mixes, compounds, and formulates pharmaceutical products. The Standard Industrial Classification code is 2834, Pharmaceutical Compounding and Formulating.

Two minor permit modification applications to this facility's previous Title V permit, R30-06100033-2006 (MM06 & MM07) are incorporated into this Title V permit renewal.

Emissions Summary

Plantwide Emissions Summary [Tons per Year]		
Regulated Pollutants	Potential Emissions	2010 Actual Emissions
Carbon Monoxide (CO)	81.1	11.14
Nitrogen Oxides (NO _x)	61.9	5.82
Particulate Matter (PM ₁₀)	76.76	1.85
Total Particulate Matter (TSP)	76.76	1.85
Sulfur Dioxide (SO ₂)	0.6	0.05
Volatile Organic Compounds (VOC)	156.1	112.37
<i>PM₁₀ is a component of TSP.</i>		
Hazardous Air Pollutants	Potential Emissions	2010 Actual Emissions
Acetonitrile	- ¹	0.2431
Methanol	- ¹	0.3211
All other HAPs	- ¹	0.166
Total HAPs	24.4	0.71

Some of the above HAPs may be counted as PM or VOCs.

¹Specific PTE information not provided in permit application; permit application states the maximum potential emission for any HAP is 9.4 TPY.

Title V Program Applicability Basis

This facility has the potential to emit 156.1 TPY of VOCs. Due to this facility's potential to emit over 100 tons per year of criteria pollutant, Mylan Pharmaceuticals, Inc. is required to have an operating permit pursuant to Title V of the Federal Clean Air Act as amended and 45CSR30.

Legal and Factual Basis for Permit Conditions

The State and Federally-enforceable conditions of the Title V Operating Permits are based upon the requirements of the State of West Virginia Operating Permit Rule 45CSR30 for the purposes of Title V of the Federal Clean Air Act and the underlying applicable requirements in other state and federal rules.

This facility has been found to be subject to the following applicable rules:

Federal and State:	45CSR2	Particulate matter air pollution
	45CSR6	Open burning prohibited
	45CSR7	Particulate matter air pollution from manufacturing processes
	45CSR10	Emissions of sulfur oxides
	45CSR11	Standby plans for emergency episodes
	45CSR13	NSR permits
	45CSR16	New stationary sources
	WV Code § 22-5-4 (a) (14)	The Secretary can request any pertinent information such as annual emission inventory reporting.
	45CSR30	Operating permit requirement.
	40CFR60, Subpart Dc	Small industrial-commercial-institutional Steam generating units
	40CFR60, Subpart JJJJ	Stationary spark ignition (IC) engines
	40 C.F.R. Part 61	Asbestos inspection and removal
	40 C.F.R. Part 82, Subpart F	Ozone depleting substances
State Only:	45CSR4	No objectionable odors

Each State and Federally-enforceable condition of the Title V Operating Permit references the specific relevant requirements of 45CSR30 or the applicable requirement upon which it is based. Any condition of the Title V permit that is enforceable by the State but is not Federally-enforceable is identified in the Title V permit as such.

The Secretary's authority to require standards under 40 C.F.R. Part 60 (NSPS), 40 C.F.R. Part 61 (NESHAPs), and 40 C.F.R. Part 63 (NESHAPs MACT) is provided in West Virginia Code §§ 22-5-1 *et seq.*, 45CSR16, 45CSR34 and 45CSR30.

Active Permits/Consent Orders

Permit or Consent Order Number	Date of Issuance	Permit Determinations or Amendments That Affect the Permit (<i>if any</i>)
R13-2068O	September 14, 2011	
G60-C016	April 7, 2010	
G60-C035	June 24, 2011	

Conditions from this facility's Rule 13 permit(s) governing construction-related specifications and timing requirements will not be included in the Title V Operating Permit but will remain independently enforceable under the applicable Rule 13 permit(s). All other conditions from this facility's Rule 13 permit(s) governing the source's operation and compliance have been incorporated into this Title V permit in accordance with the "General Requirement Comparison Table B," which may be downloaded from DAQ's website.

Determinations and Justifications

Incorporated into this Renewal is a Minor Modification for this facility's previous Title V Permit, R30-06100033-2006 (MM06). These changes incorporated revisions made in R13-2068O. As stated on page 1 of R13-2068 these changes address the following:

1. Increase the permitted capacity of various fluid beds (533, 534, 535, 536, 537, 538, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, and 582)
2. Addition of an absorber (10008538) to the permit
3. Controlling two fluid beds (573, 579) with the absorber (10008538)
4. Controlling of two coating pans (244, 245) with the RTO (10008085), and
5. Controlling the previously grandfathered ovens (oven 18, oven 19, oven 681, and oven 682) with the RTO (10008085).

To accomplish the necessary changes, the following language was revised in this Title V permit:

- The emission units table was updated in accordance with items 1-5 above.
- The particulate matter limits for the boilers was updated for conditions 4.1.4 and 4.1.6 to include PM_{2.5} and condensables.
- Condition 5.1.2 was revised so that Fluid Bed particulate matter emission limits would include PM_{2.5} and PM₁₀.
- The Fluid Bed per-load material loading limits were increased in conditions 5.1.3(a)(1) and (2).
- Language was added to condition 5.1.3(f) for Fluid Beds 573 and 579 to exhaust to Absorber for control of VOCs or directly to atmosphere.
- A new VOC hourly limit for Fluid Beds exhausting to the Absorber was added to condition 5.1.4.
- The total combined annual VOC emissions to the atmosphere from all Fluid Beds were reduced in condition 5.1.5.
- Language in condition 5.2.5 was revised to address VOC reductions from the Absorber. This revision includes the addition of language for Fluid Beds 573 and 579. Previously, these fluid beds exhausted VOCs directly to the atmosphere, not to any control device.
- Condition 7.1.3 was revised so that Coating Pan particulate matter emission limits include PM_{2.5} and PM₁₀. Additionally, the emissions limit for coating Pan 215 was increased from 0.56 lb/hr to 0.84 lb/hr.
- Condition 7.1.4 was revised to reduce maximum VOC emissions for Coating Pans 244 and 245 from 396.9 lb/hr to 7.94 lb/hr (as emitted from the RTO) if venting exhaust to the RTO for the purpose of controlling VOC emissions.
- Language was added as condition 7.1.6(f) for Coating Pans 244 and 245 to exhaust to the RTO for control of VOCs or directly to atmosphere.
- Language in condition 7.2.5 was revised to include additional monitoring and recordkeeping for Coating Pans 244 and 245 when venting exhaust to the RTO.
- Coating Pans 244 and 245; and Oven Dryers 260-263 were added to the RTO requirements in conditions 8.1.5, 8.1.7, and 8.2.3.
- Section 10.0 was added to this permit. This section lists requirements specifically for the Oven Dryers.
- Section 11.0 was added to this permit. This section lists requirements specifically for the Absorber.

Incorporated into this Renewal is a second Minor Modification for this facility's previous Title V Permit, R30-06100033-2006 (MM07). These changes incorporated the addition of a second Kohler 100 REZG natural gas fired emergency generator, permitted under G60-C035. The following changes were made to this Title V permit as a result:

- The new generator (emission unit: 10008594) was added to the emission units table.

- This new generator has the same fuel and emission requirements as the previously installed generator (EG01). Therefore, the only other necessary permit change was to add references for permit G60-C035, which authorizes use of this generator, to conditions 9.1.1 and 9.1.2.

In addition to the previously mentioned changes, there are only formatting and boilerplate changes made with this permit renewal.

Compliance with the PM limits in conditions 5.1.2, 6.1.2, 6.1.3, 7.1.2, 7.1.3, 8.1.1, and 8.1.3 are demonstrated by throughput limits throughout the permit.

Greenhouse Gas Tailoring Rule: This is a renewal Title V Permit and there have been no changes that would have triggered a PSD permit. As such, there are no applicable GHG permitting requirements.

Non-Applicability Determinations

The following requirements have been determined not to be applicable to the subject facility due to the following:

45CSR27 – To Prevent and Control the Emissions of Toxic Air Pollutants. This rule does not apply to the facility because the facility currently does not have the potential to emit any such toxic air pollutants in quantities equal to or greater than those set forth in this rule.

40 C.F.R. 60, Subpart Ka – Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978 and Prior to July 23, 1984. This subpart does not apply to the storage tanks at the facility because the tanks do not contain petroleum liquids and the tanks have a capacity less than those tanks defined as an affected facility.

40 C.F.R. 60, Subpart Kb – Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984. This subpart does not apply to the storage tanks at the facility because the tanks were installed prior to the commencement of construction date and the tanks have a capacity less than those tanks defined as an affected facility.

40 C.F.R. 63, Subpart F – National Emissions Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry. The facility does not manufacture as a primary product any of the chemicals listed in Table 1 of Subpart F.

40 C.F.R. 63, Subpart G – National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater. Since the facility is not subject to Subpart F of this part, it inherently is not subject to Subpart G.

40 C.F.R. 63, Subpart FFFF – National Standards for Miscellaneous Organic Chemical Manufacturing. The facility does not emit hazardous air pollutants at major levels and is therefore not subject to this subpart.

40 C.F.R. 63, Subpart GGG – National Standards for Pharmaceuticals Production. The facility does not emit hazardous air pollutants at major levels and is therefore not subject to this subpart.

40 C.F.R. 63, Subpart DDDDD – National Standards for Industrial, Commercial, and Institutional Boilers and Process Heaters. The facility is not a major source of hazardous air pollutants and is therefore not subject to this subpart.

40 C.F.R. 63, Subpart VVVVVV – National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources. Mylan has stated that all HAP emissions are from the quality control laboratories, which are exempt from this subpart according to 40 C.F.R. § 63.11494(c)(4).

40 C.F.R. Part 64 - Compliance Assurance Monitoring. This is the second permit renewal for this facility. At the time of the first renewal, CAM was determined not to be applicable to the sources currently in use at the facility. Since the first renewal, several new pieces of equipment were installed at this facility. This equipment includes fluid beds (574, 575, 576, 577, 578, and 579), the RTO (10008085), the Absorber (10008538), and the Emergency Generators (EG01 and 10008594).

The RTO and absorber serve as the control devices for the fluid beds, coating pans, and ovens (as applicable). The PTE of any unit being routed to a control device for that pollutant is less than 100 TPY, therefore CAM still does not apply.

45CSR§2-5.1 – Control of Fugitive Particulate Matter. The facility burns natural gas, therefore this section of Rule 2 does not apply in this situation.

45CSR10 – To Prevent and Control Air Pollution from the Emission of Sulfur Oxides

45CSR§10-4 – Standards for Manufacturing Process Source Operations. The facility's manufacturing process source operations do not emit sulfur dioxide, other than trace amounts from natural gas combustion.

45CSR§10-5 & 45CSR§10-8 – The facility's boilers only burn natural gas, and therefore are exempt from the requirements of sections 5 (*Combustion of Refinery or Process Gas Streams*) and 8 (*Testing, Monitoring, Recordkeeping and Reporting*).

45CSR10A – Testing, Monitoring, Recordkeeping and Reporting Requirements Under 45CSR10. The facility's boilers only burn natural gas, and therefore are exempt from the requirements of this rule.

Request for Variances or Alternatives

None.

Insignificant Activities

Insignificant emission unit(s) and activities are identified in the Title V application.

Comment Period

Beginning Date: November 3, 2011

Ending Date: December 5, 2011

All written comments should be addressed to the following individual and office:

Rex Compston, P.E.
Title V Permit Writer
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304

Procedure for Requesting Public Hearing

During the public comment period, any interested person may submit written comments on the draft permit and may request a public hearing, if no public hearing has already been scheduled. A request for public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing. The Secretary shall grant such a request for a hearing if he/she concludes that a public hearing is appropriate. Any public hearing shall be held in the general area in which the facility is located.

Point of Contact

Rex Compston, P.E.
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304
Phone: 304/926-0499 ext. 1209 • Fax: 304/926-0478

Response to Comments (Statement of Basis)

The following comments were received from the EPA:

1. Page 25, Condition 3.7.2.j:

I agree that CAM does not apply, but the 64.2(b)(1)(vi) exemption does not apply because "the applicable compliance method includes an assumed control device emission reduction factor that could be affected by the actual operation and maintenance of the control device" (from 64.2(b)(1)(vi)). I think proper justification for CAM not applying is just stating that the PTE of any unit being routed to a control device for that pollutant is less than 100 TPY.

Permit writer made the suggested revision.

2. Page 27, Condition 4.2.2:

I would recommend adding a VE observation frequency (Method 22 and/or method 9). If a unit is subject to an opacity limit they need to do some form of monitoring to demonstrate compliance with that limit.

Permit writer's response: The units this requirement applies to are boilers that burn natural gas. Since they burn natural gas, there will be very little, if any, visible emissions making VE observations unnecessary. This particular requirement is a relic of past permitting language.

3. Page 30, Condition 5.1.5.b:

The date says as of October 1, 2011. This seems to be inconsistent with 10.1.2 (October 1, 2012) Is this a typo?

Permit writer's response: This is not a typo.

4. Page 30, Condition 5.2:

There doesn't appear to be any monitoring associated with the PM limits in 5.1.2. Every limit has to have monitoring associated with it to demonstrate compliance. If the throughput limits are what is being used to indirectly monitor PM limits, I would recommend adding a phrase stating this. (e.g. "Compliance with ____ is demonstrated by compliance with ____."

Permit writer added a notation in the fact sheet stating that the throughput limits are being used to demonstrate compliance.

5. Page 30, 5.2.2:

Remove "normal" from the phrase, during periods of normal facility operation. As written it is not practically enforceable.

Permit writer made this revision.

6. Page 34, 6.2:

Same comments as #4 and 5 above.

Permit writer made the suggested revisions.

7. Page 36, 7.2:

Same comments as #4 and 5 above.

Permit writer made the suggested revisions.

8. Page 40, 8.2:

Same comments as #4 and 5 above.

Permit writer made the suggested revisions.

9. Page 44, 10.1.2:

See comments #3. Is "2012" a typo?

Permit writer's response: This is not a typo.